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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,776	10/15/2003	Gary Karlin Michelson	102.0001-13000	6323
22882	7590	02/24/2006	EXAMINER	
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			BROWN, MICHAEL A	
			ART UNIT	PAPER NUMBER
			3764	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,776	MICHELSON, GARY KARLIN	
	Examiner	Art Unit	
	Michael Brown	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-138 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-138 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10-15-03, 6-10-05</u> . | 6) <input type="checkbox"/> Other: <u>IDS 10-17-05, 1-2-06</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 9-10, 14-15, 21-27, 29, 31, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Froning.

Froning discloses in figures 1-8 a method for preparing an implantation space in a vertebrae of the human spine, the method comprising the steps of positioning one end of a hollow guard 31, in contact with the exterior surface of at least one vertebrae (col. 2, lines 38-41), forming, through the hollow guard an opening 27, inserting, through the hollow guard and into the opening, an implantation material (46, 49), that is of sufficient strength to support bone of the vertebrae (col. 3, lines 4-21), the implant material rigidly stabilizing (the implant is strong enough to duplicate the normal disc), the implantation space, the method is performed without altering the height of one of the guard (the height on the ends of the guide are not altered) and inserting an instrument through the 36 the guide to access the bone of the vertebrae. As for claim 9, the method is performed without moving the hollow guard during the insertion step. As for claim 10, the inserting step includes the sub-step of inserting an implant having at least upper and lower portions that are arcuate (the implant 46 has arcuate portions along its length), along at least a portion of the implant. As for claim 14, the inserting step includes

inserting an implantation material that is not bone (the material of the bladder is not bone). As for claim 15, the inserting step includes that sub-step or inserting an implant having upper and lower portions (the upper and lower portions of 46), having at least one protrusion 49, on the upper and lower portions thereof. As for claim 21, the guide is a tubular sleeve that is at least in part hollow (fig. 2). As for claims 22-23, the positioning step includes the sub-step of positioning the guard having a length (fig. 2) defined by a distal portion and a proximal portion forming a length (fig. 2), the length having a substantially uniform cross-section along its distal end and length (fig. 2). As for claim 24, the guard has a cross sectional configuration substantially the same as the substantial uniform cross section of the guard. As for claim 25, the guard having one end having a circumference that is uninterrupted and constant (fig. 2). As for claim 26, projections (34a, 34) extending from the uninterrupted and constant circumference of the one end of the guard. As for claim 27, forming an opening having arcuate portions (the ends of 27 are arcuate). As for claim 29, positioning the one end of the guard in contact with the vertebrae (fig. 3). As for claim 31, the material of 46 can be interpreted as a biomaterial.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6, 8, 32-35, 38-39, 45-73, 75, 86-90, 95-100, 103-109, 111, 130-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning in view of Ma.

Froning discloses in figures 1-8 a method for preparing an implantation space in a vertebrae of the human spine, substantially as claimed. However, Froning doesn't disclose the step of inserting a drill into the guard or the step of positioning a portion of the hollow guard into the vertebrae or the step of inserting an inner sleeve in the guide. Ma teaches in figure 10 a method of preparing an implantation space in a vertebrae comprising inserting a drill 64 into a guide (the guide that 64 is inserted into in fig. 10) to access the vertebra with the drill, positioning a portion of the guide in the vertebrae (fig. 10) and inserting an inner sleeve 49 inside of a guide 53. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the drill as taught by Ma could be substituted for the cutting device disclosed by Froning because either device could be used to form an opening in the vertebrae. The hollow guard disclosed by Froning could be inserted into the vertebrae in order to stabilize the end of the hollow guard inside of the vertebrae. The sleeve could be inserted into the guide to allow the drill bit to be inserted into the sleeve and the hollow guide. Ma also teaches inserting a first tool 64 through the guide and then inserting a second tool into the guide (to remove any debris that the first tool leaves behind, col. 5, lines 55-63) and a material inserter (the tubular member that the plug is inside of that is inserted into the vertebrae). It is old and well known that an opening can be milled to remove debris therefrom. The implantation material disclosed by Froning has a maximum cross-section dimension perpendicular to the length (fig. 5). The implantation material is

press downwards before it is injected into the vertebrae. The maximum cross-section dimension perpendicular to the length is round in cross-section (fig. 5). It is within the scope of the invention to make the elongated portion of at least 32 millimeters because the dimension is not critical.

Claims 7, 11-13, 17-20, 28, 30, 36-37, 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning in view of Bagby.

Froning discloses in figures 1-8 a method for preparing an implantation space in a vertebrae of the human spine, substantially as claimed. However, Froning doesn't disclose step of inserting the implantation material comprising a fusion-promoting substance, the implant having a hollow interior between upper and lower arcuate portions, the step of loading the hollow interior with fusion promoting substances, loading the hollow interior with bone, the implant having a leading end and a trailing end, the step of engaging an end cap for closing the open end of the implant, the step of engaging one end of the implant, the forming step including the sub-step of forming an opening that is generally cylindrical and the step of pressing a biomaterial into the implantation space. Bagby teaches in figures 1-6 a method for preparing an implantation space in a vertebrae of the human spine comprising a fusion-promoting material (bone chips, col. 4, lines 22-25), an implant 10 having a hollow interior (fig. 4), and upper and lower arcuate portions (fig. 4), the step of loading the hollow interior with fusion promoting substance (col. 4, lines 21-26), the implant has a leading end (fig. 2), a trailing end (fig. 2) and an end cap 12, the step of engaging the end of the implant (via the prongs 21 on the insertion tool 16 going into the openings 15 in the implant), the

step of forming a cylindrical opening 29 and the step of pressing a biomaterial into implant. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the implant as taught by Bagby could be substituted for the implant disclosed by Fronging. The hollow implant would allow fusion bone growth around the implant. The hollow interior would allow bone to grow through the implant. The cap would allow the end to be removed in order to place the bone fusion material inside of the implant. The prongs and the openings on the implant would allow the implant to be engaged in order to insert it in to the vertebrae. The cylindrical opening in the vertebrae would hold the implant inside of the vertebrae. The bone chips could be pressed into the implant in order to make sure that the entire interior of the implant has bone fusion substance therein.

Claims 74, 76-80, 83-85, 92-94, 101-102, 110, 112-116, 119-126, 128-129 and 137-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over the claims as applied to claims above, and further in view of Bagby.

Bagby teaches in figures in figures 1-6 a spinal implant as set forth above. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the spinal implant having a leading end, a trailing end, bone fusion substance, a cap attached to one end, an a cylindrical opening form in the vertebrae could be substituted for the spinal implant disclosed by Fronging and taught by Ma for the reasons set forth above.

Claim s 16 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fronging in view of Brantigan '915.

Froning discloses in figures 1-8 a method for preparing a vertebrae of the human spine, substantially as claimed. However, Froning doesn't disclose the implant having projections projecting distally from one end. Brantigan teaches in figure 8 a spinal implant having projections (32c, 32d) projecting from distally from one end. The projections are threads. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the projections (49) disclosed by Froning could project distally from one end as taught by Brantigan in order to use the projections to hold the implant inside of the vertebrae.

Claims 81-82, 91, 117-118, 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims above, and further in view of Brantigan '915.

Brantigan '915 teaches in figure 8 a spinal implant having projections (32c, 32d) extending distally from one end of the implant. The projections are threads. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the projections as taught by Brantigan '915 could be incorporated into the implant disclosed by Froning for the reason set forth immediately above.

Conclusion

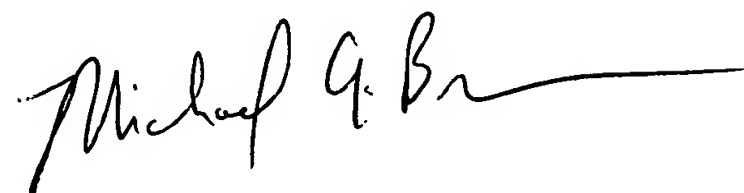
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. No additional prior art was cited during this office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 571-272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gergory Huson can be reached on 571-272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Brown
February 3, 2006

A handwritten signature in black ink, appearing to read "Michael A. Brown", with a long horizontal line extending to the right.

MICHAEL A. BROWN
PRIMARY EXAMINER